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HOW TO EVALUATE COMMERCIALLY AVAILABLE SPIROMETERS

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PART A. OBJECTIVES

Upon conclusion of this presentation, the reader will be able to:

1. Understand the performance standards for spirometers recommended by The American Thoracic Society (ATS) and the American College of Chest Physicians (ACCP).
2. Outline the sources of error in spirometry.
3. Perform simple spirometer evaluations with a calibrated syringe.
4. Compare features of available spirometers with their needs.
5. Evaluate published comparisons of spirometer performance.

PART B. ABSTRACT

There are now more than 20 manufacturers who market spirometers; many having several models. Until recently performance recommendations for spirometers have not been available. Now that performance criteria are available, users and manufacturers are anxious to meet or exceed the minimum criteria. Simple evaluation techniques using a calibrated syringe are outlined. Also, more sophisticated testing methods using standard test waveforms will be discussed.

PART C. CONTENT

The use of simple pulmonary function testing (spirometry) has come of age in the hospital and clinic. As a result the marketplace has been flooded with new spirometers. These spirometers can be inexpensive and simple (costing less than $1,000) or expensive and perhaps microcomputer based (costing $5,000 to $7,000). Each manufacturer claims that their device is the best and presents features to prove the point. The user, whether physician or technician, is then required to make some rational decision about purchase or lease of a spirometer. This presentation outlines how the user might evaluate commercially available spirometers.

PERFORMANCE RECOMMENDATIONS:

The American Thoracic Society (ATS) (1),the American College of Chest Physicians (ACCP) (2), and the Association for the Advancement of Medical Instrumentation (AAMI) (3) have all made recommendations for spirometer performance. These recommendations are roughly equivalent although the ATS and specifically the AAMI documents give more details and also provide test methods for evaluating spirometers. Table I below outlines minimum spirometer requirements.

TABLE I

RECOMMENDED MINIMUM REQUIREMENTS FOR
SPIROMETERS USED FOR PATIENT DIAGNOSIS (1)

	Range/Accuracy BTPS (Liters)	Flow Range (Liters/Sec)	Time (Sec)
FVC	7 Liters/ ±3% of Reading or ±50ml whichever is greater	0 → 12	10
FEV_1	7 Liters/ ±3% of Reading of ±5ml whichever is greater	0 → 12	1
FEF25-75%	7 Liters/ ±5% of Reading or ±0.2 Liters/Sec whichever is greater	0 → 12L	10
Recorder Volume-Time	Record at least 10 Seconds with time base of at least 2 cm/sec and volume sensitivity of at least 1 cm/liter		
Flow-Volume	Flow sensitivity of at least 0.4 cm of chart per liter/sec of flow volume sensitivity of at least 2 cm/liter.		

There have been and continue to be requests to relax the spirometer requirements for physician office or clinic use. However, since a spirometer in an office is used for diagnostic purposes, it must meet the same performance requirements as a spirometer used in a hospital pulmonary laboratory.

SOURCE OF ERROR IN SPIROMETRY:

There are several sources of error in the performance, measurement, computation and interpretation of the forced vital capacity (FVC) spirogram. All of these factors must be considered when evaluating a spirometer. The errors can be classified into five categories:

1. Patient Performance
2. Instrument Performance
3. Waveform Measurement
4. Computation
5. Data Interpretation

The categories are listed in the order that the data is acquired and processed. It should be apparent that if there is an error at any on of the steps, a subsequent measurement, computation or interpretation will also be in error. Therefore, it is crucial that proper patient performance be achieved. The ATS has suggested methods for evaluation of patient performance. (1) Lack of adequate patient performance is probably still the single largest error source in spirometry. Patient performance can best be elicited by a well trained, motivated and enthusiastic technician! There is no substitute for a good technician who can explain the spirometric test to the patient, have them perform the test adequately and eliminate poor tests from the data gathered. The human is superbly equipped to perform pattern recognition. Therefore, a trained technician can quickly and accurately evaluate volume-time or flow-volume curves for adequate quality.

Instrument performance is perhaps the mose widely studied error source. There are at least seven methods of testing spirometers. These include: 1) testing 100 subjects by having them blow into two spirometers, one of them being a "gold standard"; 2) where possible the first method can be done simultaneously with devices in series; 3) sinusoidal testing; 4) explosive decompression; 5) hand driven syringes; 6) power driven syringes with a limited number of waveforms; and 7) computer driven syringe with programmable waveforms. Except for the computer driven syringe each of the other methods has serious limitations (4). Factors which must be considered when designing a spirometer are its accuracy and precision. Accuracy refers to how well the device measures the true signal while precision refers to how repeatable the device is. For spirometry we need a device which can measure relatively slow changing signals accurately (FVC) and can also measure dynamic or time varying signals adequately (FEV_1, FEF25-75%). Factors which contribute to spirometer accuracy are its linearity, dynamic response and long term stability.

Parameter measurement from the forced spirograms can be accomplished in several ways. Perhaps the most common method is a manual reading of the volume-time curve. When a spirogram is read by any method, a set of rules must be applied to recognize the pattern in the waveform. Critical points which need to be determined are: 1) when does the expiration begin (time zero) and 2) when does it end. The "back extrapolation" method has now been accepted as a standard for determing time zero (1). Recommendations have also been made for end point selection although these are inadequate. (1) The computer has augmented our ability to measure spirograms. Factors important to determine a computer's ability to measure accurately are the data sample method, the data sampling rate and resolution. Manual measurement accuracy of volume-time spirograms depends on paper speed and volume resolution. The current recommendations for paper speed are 2 cm/sec and volume

sensitivity of 1 L/cm. (1) Recent studies we've conducted indicate that both of these may be inadequate if clinically important measurement errors are to be eliminated. This same study showed that gross human errors are common and that dual reading of spirograms may be required. Therefore, a validated computerized system will likely be the method of choice for all spirometry measurements in the future.

Computations of results from measured parameters continue to be a major source of errors. Most common of these errors is neglect or incorrect conversion from atmospheric conditions (ATPS) to body conditions (BTPS). Also, errors in computation of FEV_1/FVC ratio and comparison of results with reference (normal) values continue to be a source of error. Computational errors can be eliminated by computerized methods.

Interpretation of results can also lead to errors. Even if all the other steps are done accurately and the data presented for interpretation is "perfect", errors can still be made because of use of wrong reference (normal) values, inadequate criteria for determination of normal or categorization of severity of impairment. (5,6)

SPIROMETER EVALUATIONS:

Spirometer evaluations can take on a variety of levels of sophistication and expense. In general, three types of evaluation are needed:

1. Design validation - a complex and exhaustive set of tests usually reserved for the designer or manufacturers to assure the performance characteristics of a spirometer. Requires complex and expensive equipment.

2. Performance verification - a complete test and verification of a spirometer. Can be done by the manufacturer, a certification laboratory or a sophisticated user. (3) Requires complex and expensive equipment.

3. Quality control - This type of testing should be done primarily by the user to assure that reliable results are obtained from a spirometer.

To evaluate the dynamic characteristics of spirometers Petusevsky (7) and Glindmeyer (8) have developed and described devices which generate "exponential" volume-time spirograms. Even though these devices can test the dynamic characteristics of spirometers, they do not simulate the start and end characteristics of real patients. Therefore, a set of 24 waveforms representing a range of normal and diseased subjects with a diversity of efforts have been selected as a standard test set (3,9). These waveforms are available in a variety of computer readable forms. Commonly used spirometric parameters for each waveform are known. Since the waveforms are in digital form they can be used to drive a computer controlled syringe. (4) The syringe can then be attached to the spirometer to be tested. Then the known parameters can be compared with the measured parameters. Since the measured parameters may be obtained by computer methods, the test waveforms can be used to evaluate the hardware and software of the spirometer system. At the moment only one set of this equipment is available. Since the equipment is expensive it is unlikely to be replicated. Hopefully the need for design validation and performance verification of spirometers will encourage private industry to

develop and market inexpensive yet accurate testing devices.

Since design validation and performance verification require complex and expensive equipment, it is unlikely that these evaluation methods will have widespread user application in the near future. (3,4) Therefore, what does a user do to evaluate the performance of a spirometer? Following sophisticated evaluation of spirometers with an expensive and complex hydraulic syringe (4) it was found that most of the defects in spirometers could have been found with some simple test methods which fall in the category of quality control (10).

Five steps for spirometer quality control are recommended:

1. Simulate a patient by injecting air from a calibrated 3 liter syringe with at least two different flow ranges (2 sec injection time to simulate a normal and 6 sec to simulate an obstructed patient).

2. Check for any leaks in the tubing or spirometer. This is especially important for volume measuring spirometers.

3. Perform several FVC manuvers using yourself as a subject to:

   a. evaluate premature termination of test by automatic equipment.

   b. check the start of test criteria for a "false start".

4. Verify time base accuracy by using a stopwatch or using a calibrated syringe with an accurate FEF25-75% determination.

5. Compare automatically (computer) determined FEV_1 values with several hand measured FEV_1 values to validate correct use of back extrapolation methods for time zero determination.

FEATURE COMPARISON:

The first step in evaluating any spirometer should be to compare the manufacturer's specifications and the spirometer itself with performance recommendations, listed earlier. (1,2,3) Also, published evaluation reports should be reviewed to establish a base of comparison. (4) Once these steps are taken the user will find that there are still many devices to choose from. Following the Snowbird Conference (1) and subsequent testing (4) most spirometer manufacturers who had difficulties have corrected the problems they had with their spirometers and have introduced several new models.

Major features for comparison are shown in Table II.

TABLE II

SPIROMETER FEATURE COMPARISON

	Strength	Weakness
Flow	Small size	Questionable accuracy Lack of stability Complex sensor/compensation
Volume	More accurate More stable Simple sensor	Larger size
Computer	Save time Simplicity of use Error reduction potential Data storage & interpretation	Cost Repair complexity Hard copy of curves

PUBLISHED RESULTS:

Unfortunately there is no "consumer report" available for spirometers. The most recently published review was in 1980 on testing done in 1978. (4) Although there is hope for spirometer standards (3) and a testing methodology to validate them, promulgation of these standards are being delayed because of a lack of a suitable, inexpensive patient simulator. At one time it looked like the government would get into the spirometer test and certification business much like the EPA has measured fuel efficiency for automobiles; however, because of budget cuts the government has chosen not to do the testing. Therefore, for the near future we will have to make due with the quality control testing methods outlined above to validate spirometer performance.

CONCLUSIONS:

In 1981 nearly all commercially available spirometers probably meet requirements set by professional pulmonary organizations. Unfortunately there are no current data published which can be used as a consumer guide. Therefore, it is incumbent on users to be able to use simple testing methods to validate manufacturer claims and provide ongoing quality control in their laboratories. Methodology for this type of testing has been provided.

PART D. POST TEST

1. Which of the following organizations have written standards for spirometers?

*a. American Thoracic Soceity (ATS)
*b. American College of Chest Physicians (ACCP)
*c. Association for the Advancement of Medical Instrumentation (AAMI)
d. American Association for Respiratory Therapy (AART)

2. Which of the following are major sources of spirometry error?

a. Small changes in barometric pressure.
*b. Inadequate patient performance.
c. Small changes in room temperature.
*d. Hand measurement of waveforms.

3. Spirometers are best evaluated with a syringe with a volume of at least -

a. 100 ml
b. 500 ml
c. 1000 ml
*d. 3000 ml

4. Important features to consider when purchasing a spirometer are -

*a. Volume vs flow sensor
b. Color of chart paper
*c. Meeting ATS recommendations
*d. Paper speed

5. Published comparison of spirometer performance are -

*a. Available in the literature.
b. Available from the government.
c. Available from manufacturers.
d. Available from a certification laboratory.

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